

COLORADO STATE BOARD OF PHARMACY
February 18, 2010

Minutes

The Colorado State Board of Pharmacy meeting was convened by President Rich Doyle, R.Ph., at approximately 8:30 a.m. on Thursday, February 18, 2010 at 1560 Broadway, Conference Room 1550 (Large), Denver, CO 80202. Notice of this meeting was given in accordance with Division of Registrations Policy Number 80-17.

Board members attending were: Mary K. Arceneaux, R.Ph., Jeannine G. Dickerhofe, R.Ph., Rich Doyle, R.Ph., Katherine Edelblut, R.Ph., Paul Limberis, R.Ph., and Averil Strand, R.N.

Staff members attending were Wendy Anderson, R.Ph., Program Director; Chief Inspector, Chris Gassen, R.Ph.; Tia Johnson, Complaint/Licensing Specialist; Susan Martin, R.Ph., Inspector; and Mark O'Neill, R.Ph., Inspector. Also present was Jo Kaye, Assistant Attorney General, to advise the Board.

APPROVAL OF MINUTES

The Board approved the minutes from the January 21, 2009 meeting as amended.

ADDITIONS TO THE AGENDA

- Medical Marijuana, Presentation by Jeannine Dickerhofe, RPh
- Case 2010-2951 – Brendan J. Ricklefs
- Board Member Training in Executive Session

APPEARANCES

None

HEARINGS

None

REPORTS

President's Remarks

None

Program Director's Report

Ms. Anderson requested that the Board consider deleting Board Policy 20-6, regarding nuclear pharmacist certification, due to 2009 amendments that were made to Board Rule 12.00.00 which, among other things, eliminated a requirement of the Board to certify nuclear pharmacists. The Board voted to delete Board Policy 20-6.

Ms. Anderson announced that the regularly scheduled March 18, 2010 Board meeting is cancelled and that the next regularly scheduled Board meeting is April 15, 2010.

The Board then discussed whether it should still have a Rules Committee. After due consideration, the Board voted to disband the Rules Committee. The Board did, however, decide that the committee should finalize its work on the issue it is currently working on.

Colorado Pharmacists Society (CPS) – Rich Doyle, RPh

Advances in Pharmacy Practice, a Continuing Education (“CE”) program providing 6 hours of ACPE approved continuing education, is being offered by CPS and the School of Pharmacy on February 20, 2010. The program will cover the topics of pain management, osteoporosis, alternative & complementary medicine, HIV/AIDS, new drugs, and pharmacy law.

The CPS Annual Summer Meeting will be June 17-19, 2010 in Estes Park where 10 hours of CE will be offered.

The Colorado Pharmacists Society is once again a partner of the 9 Health Fair which will be held April 17-25, 2010. CPS is helping the Fair organizers get pharmacist volunteers for designated sites throughout Colorado. CPS will post volunteer information on its website.

The Colorado Department of Public Health and Environment (CDPHE), CPS and a consortium of concerned organizations have launched a pilot program offering a secure and environmentally responsible way for people to dispose of unwanted medicines. Tamper-resistant collection boxes are now available at locations around the Denver metro area, including several King Soopers stores, two Tri-County Health Department offices and Denver Health Medical Center. The CDPHE has contracted with the waste management firm, Curbside Inc., to install the secure collection boxes and to collect and dispose of the waste medicines. The boxes are intended for household medications, including prescription drugs and over-the-counter products. Controlled substances, medications from clinics, hospitals and nursing homes may not be disposed of through these boxes.. A guidebook attached to each collection box will explain which products can be deposited. Through February 15th, 2010, Curbside has collected 683 pounds of materials. Surveys of users give high ratings to the project.

Governor’s Expert Emergency Epidemic Response Committee (GEEERC) – Paul Limberis, RPh

Mr. Limberis stated that while there is no report at this time, the next meeting of the GEEERC is scheduled for April 1, 2010.

Intern & School Relations – Jeannine Dickerhofe, RPh

Ms. Dickerhofe gave the report. The University of Colorado has updated its drug policy to prohibit the use of medical marijuana on its campuses, even when recommended by a prescribing practitioner.

The Regis University School of Pharmacy began its Introductory Pharmacy Practice Experience (IPPE) program in January 2010, and positive responses have been received from its faculty.

Legislation - Jeannine Dickerhofe, RPh.

Ms. Dickerhofe gave the report. Senate Bill 10-117 would add over-the-counter medications identified through the drug utilization review process to services provided under Medicaid when the medications are prescribed by a licensed practitioner or a qualified licensed pharmacist. The Medical Services Board would be required to adopt rules to allow pharmacies to be reimbursed for dispensing the specific medications to Medicaid recipients and to identify the standards for qualified pharmacists.

Senate Bill 10-126 would enact the "Pharmaceutical Transparency Act" to require manufacturers of drugs and medical devices, for which payment is available under Colorado's Medicaid Program or the Children's Basic Health Plan, to submit an annual transparency report to the Colorado Secretary of State. The report would detail information regarding payments made by a manufacturer to a health care practitioner during the preceding calendar year.

House Bill 10-1216 would, among other things, permit a prescription drug outlet to allow a pharmacist to take vaccines off its premises for administration to a patient.

Rules – Rich Doyle

Mr. Doyle gave the report. The Rules Committee met on February 3, 2010 to discuss the issue of returning the contents of returned-to-stock prescriptions into automated cassettes that had been referred to it by the Board. While no decision has been made on this issue, a site visit will be part of the next Rules Committee meeting.

Inspectors

The Board reviewed an Agenda Memorandum from Mr. Gassen concerning Brendan J. Ricklefs, RPH 17609.

The Board voted unanimously to refer the matter to executive session for discussion of possible disciplinary action.

After executive session, the Board found that the public health, safety, or welfare imperatively required emergency action and voted to summarily suspend Mr. Ricklefs' pharmacist license should he fail to enter into an interim cessation of practice agreement with the Board within 10 business days.

OLD BUSINESS

Stipulations

Robert E. Lapp, RPH 11555

The Board reviewed an Agenda Memorandum from Ms. Johnson concerning Mr. Lapp's compliance with his Stipulation and Final Agency Order. The Board voted unanimously to refer the matter to executive session.

After executive session, the Board noted the information and voted to send Mr. Lapp a letter of guidance directing him to focus on his dispensing practice and recommend that he complete continuing education pertaining to the prevention of dispensing errors.

Todd B. Robbins, RPH 15952

The Board reviewed an Agenda Memorandum from Ms. Johnson. The Board voted unanimously to refer the matter to executive session.

After executive session, the Board voted to re-refer the matter for discipline.

NEW BUSINESS

Complaints

DRG Pharmacy, LLC, OSP 5826 **2010-2038**

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

ESI Mail Pharmacy Service, Inc., OSP 5851 **2010-2352**

The Board voted unanimously to dismiss the case with a letter of guidance advising ESI Mail Services, Inc. to respond to all future Board requests within the prescribed time period.

King Soopers Pharmacy # 28, PDO 9-11 **2010-0993**

Mary K. Arceneaux, R.Ph. recused.

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted unanimously to dismiss the case as being without merit.

Janet L. Hayward, RPH 11548 **2010-2196**

Mary K. Arceneaux, R.Ph. recused.

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

King Soopers Pharmacy # 80, PDO 80-30 **2010-1625**

Mary K. Arceneaux, R.Ph. recused.

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to dismiss this case as being without merit.

However, the Board directed its staff to initiate a separate complaint against the pharmacy registration of King Soopers Pharmacy # 80 for its alleged failure to: (1) post a required notice detailing the manner in which it records the identity of pharmacists conducting the initial interpretation of prescription orders and final evaluation of prescriptions; (2) accurately detail the dispensing date on prescription orders; and (3) accurately identify, on each prescription order, the pharmacist conducting the initial interpretation of new prescription orders.

Paul R. Lovelace, RPH 10399

2010-2204

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to refer the case for discipline.

McKesson Medical Surgical, WHI 6039

2010-2095

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time. The Board also voted to issue a letter of guidance advising McKesson Medical Surgical to submit complete applications to the Board in the future.

Kimberly M. McSweeney, RPH 15242

2010-1907

Mary K. Arceneaux, R.Ph. recused.

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to refer the case for discipline.

Salem R. Montez, RPH 15006

2010-2115

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to issue a Letter of Admonition for violations of the Pharmaceuticals and Pharmacists Act.

Trang Doan Thi Nguyen, RPH 17709

2010-2125

Mary K. Arceneaux, R.Ph. recused.

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted unanimously to dismiss the case as being without merit.

Elaine K. Thannum, RPH 17908

2010-2195

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to refer the case for discipline.

Janet Wheeler-Kitzman, RPH 17691

2010-1709

Mary K. Arceneaux, R.Ph. recused.

The Board voted unanimously to refer the case to executive session for discussion of possible disciplinary action.

After executive session, the Board voted to dismiss the case. The Board found that there was no reasonable cause to warrant further action at this time.

LICENCING/REGISTRATION

MedLine Industries, Inc., Non-Resident Wholesaler Applicant

The Board reviewed an Agenda Memorandum from Ms. Johnson and voted unanimously to refer the matter to executive session.

After executive session, the Board voted to deny the application and offer a probationary license.

Teleflex Medical, Inc., Non-Resident Wholesaler Applicant

The Board reviewed an Agenda Memorandum from Mr. Gassen and voted unanimously to refer the matter to executive session.

After executive session, the Board voted to deny the application and offer a probationary license.

TYCO Healthcare, Non-Resident Wholesaler Applicant

The Board reviewed an Agenda Memorandum from Ms. Johnson and voted to approve the application.

Patrick J. Marks, Pharmacist Applicant

The Board reviewed an Agenda Memorandum from Ms. Johnson and voted to approve the application.

Petra A. Abram, RPH 16698

The Board reviewed an Agenda Memorandum from Ms. Johnson and determined no further action was needed.

Paula Petersburg, RPH 12759

The Board reviewed an Agenda Memorandum from Ms. Johnson and determined no further action was needed.

Trbovich O. Laurence, RPH 14346

The Board reviewed an Agenda Memorandum from Ms. Johnson and determined no further action was needed.

Connie L. Werbelow, RPH 12208

The Board reviewed an Agenda Memorandum from Ms. Johnson and determined no further action was needed.

MISCELLANEOUS

Correspondence, etc.

Discount Pet Drugs – Plattsburg, NY

The Board reviewed an Agenda Memorandum from Mr. Gassen and determined that, due to a lack of sufficient evidence, no action could be taken at this time. The Board noted that this matter has already been referred to the New York State Board of Pharmacy.

New Regulations for Pharmacists, Request from Marybeth Schombert, Health and Safety Institute

After review of the available information, the Board voted unanimously to refer the matter to executive session for legal advice.

After executive session, the Board determined that Ms. Schombert's request is permissible under its current rules.

Peer Assistance Services – 2nd Quarter Report

The Board noted the report.

Request from St. Mary's Hospital

After review of the available information, the Board determined that the request from St. Mary's Hospital did not constitute the practice of pharmacy.

2010 ANNUAL PLANNING MEETING

Board Rule 21.00.00

The Board discussed the requirement of formulation records in hospital pharmacy settings and its application to compounded intravenous preparations that are dispensed pursuant to a patient-specific chart order as opposed to compounded intravenous preparations prepared in batch-form prior to the existence of an order. While the Board determined that the mixing of ingredients, according to manufacturer instructions, is not considered compounding under the current rule, Mr. Limberis and Ms. Edelblut will research the matter further and report to the Board at a future meeting.

Pharmacy Refrigeration and Monitoring Devices

The Board discussed a proposed requirement of pharmacies to monitor and record temperatures of drug storage refrigerators and freezers each calendar day. In addition, the Board discussed a proposed requirement of pharmacies to follow-up if refrigerator or freezer temperatures fall out of the respective ranges established by the United States Pharmacopeia (USP). After consideration of the available information, the Board directed its staff to write a statement in a future Board newsletter recommending that pharmacies carefully monitor refrigerator and freezer temperatures and to follow-up when needed. In addition, the Board directed its staff to write proposed amendments to its current regulations governing the use of refrigerators and additional language to include the use of freezers for consideration at a future meeting.

Pharmacy Waste

After consideration of the available information regarding prescription drug waste procedures, the Board determined that Colorado law does not currently address this issue

and that legislative action would be required in order for the Board to consider promulgating regulations regarding prescription drug waste.

Medical Marijuana

After consideration of the available information regarding medical marijuana, the Board determined that Colorado law does not currently give the Board the authority to regulate medical marijuana.

EXECUTIVE SESSION

At 12:10 pm Board President Rich Doyle moved that the Board enter into Executive Session to discuss with counsel disputes that are the subject of pending or imminent litigation, specific claims or grievances, or legal advice on specific legal questions, pursuant to CRS section 24-6-402 subsection (3)(a) roman (II), and matters required to be kept confidential by federal law or rules or state statutes pursuant to CRS sections 24-6-402 subsection (3)(a) roman (III) and 12-22-125.2 subsection (7)(a) including:

- Discussion with Counsel regarding the Case Status Report for matters that have been referred to the Expedited Settlement Program, including settlement negotiations, counteroffers and other legal questions;
- Discussion with Counsel regarding the legal basis for potential application denial, confidential letters of concern, disciplinary action, and, where warranted, recommended settlement guidance regarding all matters referred to Executive Session earlier in the meeting;
- Discussion of the Legal Report.

Mr. Doyle further moved that the Board enter into Executive Session for the purpose of discussing reports of malpractice claim settlements required to be kept confidential by federal law or rules or state statutes pursuant to CRS 24-6-402 subsection (3)(a) roman (III), and CRS section 12-22-113.5 subsection 3, including a malpractice settlement report with no assigned case number.

In addition, the Board President moved that the Board enter into Executive session for the purpose of discussing matters required to be kept confidential by federal law or rules or state statutes pursuant to CRS section 24-6-402 subsection (3)(a) roman (III).

Patient medical records are confidential pursuant to CRS section 25-1-1201 et seq. and CRS 13-90-107 subsection (1)(d). Drug and alcohol treatment records are also confidential pursuant to 42 Code of Federal Regulations Part 2, Article 21, Part 12, and CRS section 13-90-107.

The motion was seconded. The vote was unanimous with five votes approving the motion to go into Executive Session and none opposing.

The Board exited Executive Session at 3:25 pm.

Open Session

Malpractice Case Settlement Report

The Board voted that no further action is needed regarding the information in the report. However, the Board directed its staff to send the involved pharmacy a letter reminding it to provide future settlement reports, if available, to the Board within the required time frame as specified in Board Rule 9.00.00.

ADJOURNMENT

The Board adjourned at approximately 3:33 p.m.

Approved by Rich Doyle, R.Ph., President Date: April 15, 2010